K011766

JUL - 3 2001

510(k) Summary
(As required by 21 CFR 807.92)

A. Submitter Information

Submitter's Name:	St. Jude Medical, Daig Division
Address:	14901 DeVeau Place Minnetonka, Minnesota 55345-2126 U.S.A.
Telephone Number:	(952) 352-9716
Contact Person:	Angela Byland
Date Submission Prepared:	June 6, 2001

B. Device Information

Common or Usual Name:	Evaluator^{M} Electrophysiology Catheter
Classification Name:	Electrode Recording Catheter
Predicate Device:	Response™ Electrophysiology Catheter St. Jude Medical, Daig Division
Device Description:	The Evaluator™ Electrophysiology Catheter is a fixed-curve, electrode recording catheter with ring electrodes that are electrically coupled to conductor wires to pace the heart and sense and record bipolar intracardiac electrograms.
Intended Use:	The St. Jude Medical electrophysiology catheters can be used in the evaluation of a variety of cardiac arrhythmias.

C. Comparison of Required Technological Characteristics

All technological characteristics of the Evaluator™ Electrophysiology Catheters are substantially equivalent to the predicate device including product design, packaging, sterilization, and labeling.

D. Support of the Substantial Equivalence

St. Jude Medical, Daig Division considers the Evaluator™ Electrophysiology Catheters to be substantially equivalent to the predicate device, Response™ Electrophysiology Catheters.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL - 3 2001

Ms. Angela Byland
Senior Regulatory Affairs Manager
St. Jude Medical, Daig Division
14901 DeVeau Place
Minnetonka, MN 55345

Re: K011766
Trade Name: Evaluator™ Electrophysiology Catheter
Regulation Number: 870.1220
Regulatory Class: II (two)
Product Code: 74 DRF
Dated: June 6, 2001
Received: June 7, 2001

Dear Ms. Byland:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish

further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

for James E. Dillard III
Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K011766

Device Name: St. Jude Medical, Daig Division™ Electrophysiology Catheter (Evaluator™)

Indications for Use:

The St. Jude Medical electrophysiology catheters can be used in the evaluation of a variety of cardiac arrhythmias.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Cardiovascular & Respiratory Devices
510(k) Number K011766

Prescription Use ✓ OR Over-The-Counter Use
(Per 21 CFR 801.109)

(Optional Format 1-2-96)